DEC 16 2005

K 052604

# Appendix IV

## Summary of Safety &

## Effectiveness Information

| **Summary of Safety and Effectiveness Information**<br>Section 510(k) Premarket Notification | ***StarLite 2006 Laser Optical Fiber*** |
|---|---|

**Regulatory Authority:** Safe Medical Devices Act of 1990, 21 CFR 807.92

1. **Device Name:**

   **Device trade Name: StarLite 2006**
   **Common Name:** Laser Accessory
   **Classification Name:** Laser Instrument, Surgical, Powered

2. **Establishment Name & Registration Number:**

   **Name: Laser Dental Innnovations**
   **Number: 3003610527**

3. **Classification:**
   **878.4810** Laser surgical instrument for use in general and plastic surgery and in dermatology
   **874.4500** Laser, ENT
   **874.4490** Laser, Otolarngology
   **874.4550** Laser, Surgical, Gynecological

4. **Device Class:** Class II for all requested indications
   **Classification Panel:** General and Plastic Surgery & others
   **Product Codes:** GEX

5. **Performance Standards:**
   Various voluntary performance standards are utilized. Voluntary standards include Standard Operating Procedures , vendor and process certification and qualification procedures.

6. **Special Controls:**
   LDI, Inc. is in compliance with special controls as outlined in 21 CFR Part 1040 - Performance Standards for Light-Emitting Products. See 21 CFR §1040.10, Laser products.

7. **Equivalent or Comparison Devices:** (legally marketed)
   1. Biolase Twilight: K991994
   2. Premier Aurora: K992374
   3. Zap Softlase: K021227
   4. ADT Diolase: K951269
   5. Hoya Diodent

The StarLite fiber functions in exactly the same way as fiber optics included with the above laser systems. StarLite uses the same type of connector, fiber and fiber sizes and does not change the function or performance of the laser beam. The materials used in the Starlite are the same or are the functional equivalent as those used in the above cleared laser systems.

**8. Device Description:**

**Background.** The *StarLite 2065* is an "after-market" accessory for use with an existing surgical laser system. The device is used as a complete system (optical fiber and connector) The *StarLite 2006* is used as a direct replacement for the laser optical fiber supplied as original equipment or the original equipment laser optical fiber.

One of the primary considerations when using a fiber-optically delivered surgical laser system is that the fiber is capable of delivering the maximum amount of energy the laser is set for minus a small connector loss.

Most fiber based laser systems include a handpiece that clasps or grips the laser fiber on its protective jacket. For this reason the laser fiber must have an outside coating capable of protecting the inner core.

Many procedures call for the use or application of a "bare fiber" to the operative tissue; the so called "contact mode" of operation.

The *StarLite* is designed using industry standard connectors and optical fiber. The components of this fiber optic assembly are the same as what is currently being used on cleared existing lasers cited above. The protective outside buffer or jacket is compatible with all handpieces designed for this fiber type.

The *StarLite* laser fiber optic is intended for use with lasers that do various surgical procedures. The StarLite is universal in nature and is intended to be used on currently FDA cleared soft tissue lasers. The StarLite assembly is designed to accommodate hard clad laser fibers including 200, 300, 400 and 600 micron diameters.

**9. Cleared Indications for use:**

The StarLite is cleared for the same cleared indications of use as the laser system to which it is attached.

**10. Applicant/ Sponser Name/ Address:**

Laser Dental Innovations
745 Dubanski Drive
San Jose, CA 95123
877-753-5054

**11. Company Contact:**

Mr. Howard Feinberg
Laser Dental Innovations
745 Dubanski Drive
San Jose, CA 95123
877-753-5054

**12. Submission Correspondent:**

Mr. Howard Feinberg
Laser Dental Innovations
745 Dubanski Drive
San Jose, CA 95123
877-753-5054

**13. Sterilization Information:**

The laser optical fiber may be sterilized and/or re-sterilized until 1 meter remains. After cleaning and inspection, standard autoclave flash processing at 270 degrees F. for 30 minutes will produce a sterility assurance level (SAL) of 10$^{-6}$.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 16 2005

Mr. Howard Feinberg
Laser Dental Innovations
745 Dubanski Drive
San Jose, California 95123

Re: K052604/S1
Trade/Device Name: StarLite® 2006
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: II
Product Code: GEX
Dated: October 19, 2005
Received: October 21, 2005

Dear Mr. Feinberg:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Barbara Brehm MD
for

Mark N. Melkerson
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

## Statement of Intended Use:



**510(k) Number:** K052604

**Device Name:** *StarLite® 2006*

**Indications for Use:**

The Starlite 2006 will be used with the following lasers for the excision, ablation, vaporization and hemostasis of soft tissue.

Diolase ST produced by American Dental Technologies (810 Nm operating wavelength)
Twilight produced by Biolase (810 Nm operating wavelength)
Diodent produced by Hoya Con Bio (810 Nm operating wavelength)
Softlase produced by Zap Lasers (810 Nm operating wavelength)
Aurora produced by Premier Lasers (810 Nm operating wavelength)

indications of use summary statement:
The StarLite laser fiber optic can be used for all the of the lasers cited above as well as other diode soft tissue lasers operating using the same wavelengths.

The StarLite will become an intergral part of the laser system and by default be cleared for the same exact indications and procedures as the laser it is deployed on.

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NECESSARY

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____

(Per 21 CFR 801.109) (Optional format 1-2-96)

Barbara Bochus for MKM

**(Division Sign-Off)**
**Division of General, Restorative, and Neurological Devices**

**510(k) Number** K052604